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June 1, 2004

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Art Unit: 1638
Examiner: Phuong T. Bui
Conf. No.: 1056

Re: U.S. Patent Application Serial No. 09/938,294 filed August 24, 2001
Inventors: Gregory J. HINKLE *et al.*
Title: Novel Plant Transcribed Regions and Uses Thereof
Atty Docket: 16517.253

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

1. Appellant's Brief (in triplicate), with attached Appendix A; and
2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

Authorization is hereby given to charge the statutory fee of $330.00 for filing Appellant's Brief to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.253. A duplicate copy of this letter is enclosed.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.253. A duplicate copy of this letter is enclosed.

Sincerely,

David R. Marsh (Reg. No. 41,408)
Holly Logue Prutz (Reg. No. 47,755)

Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:	Conf. No.: 1056
Gregory J. HINKLE *et al.*	Art Unit: 1638
Appln. No.: 09/938,294	Examiner: Phuong T. BUI
Filed: August 24, 2001	Atty. Docket: 16517.253

Title: **Novel Plant Transcribed Regions and Uses Thereof**

APPELLANT'S BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Mail Stop Appeal Brief - Patents

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-captioned patent application. A Notice of Appeal was filed on March 31, 2004.

Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

The Appellant is unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 1-5, 8-10 and 14-18 are pending. Claims 1-5, 8-10 and 14-18 stand finally rejected under 35 U.S.C. §§ 101 and 112, first paragraph. Claims 1-5, 8-10 and 14-18 also stand finally rejected under 35 U.S.C. § 112, second paragraph. Appellant appeals all of the rejections of claims 1-5, 8-10 and 14-18.

4. Status of Amendments

Appellant has not filed any amendments in this case subsequent to the Final Office Action mailed December 31, 2003 ("Final Action").

5. Summary of Invention

The present invention provides a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 2 or the complement thereof. Specification at page 2, lines 15-17. The present invention also provides a substantially purified nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 2 or complement thereof. *Id.* The present invention additionally provides a substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 2 or the complement thereof. *Id.* at page 12, line 14 through page 13, line 4. The present invention further provides a substantially purified nucleic acid molecule that encodes a protein comprising an amino acid sequence of SEQ ID NO: 45. *Id.* at page 14, lines 1-4. The present invention also provides a transformed plant having a nucleic acid molecule which comprises: (A) an exogenous promoter region which functions in a plant cell to cause the production of a mRNA molecule; (B) a structural nucleic acid molecule encoding a protein comprising an amino acid sequence of SEQ ID NO: 45; and (C) a 3' non-translated sequence that functions in the plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of the mRNA

molecule. Specification at page 3, lines 8-15. The present invention also provides a transformed cell or organism comprising a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 2 or the complement thereof. *Id.*

6. Issues

The issues in this Appeal are:

(a) whether claims 1-5, 8-10 and 14-18 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(b) whether claims 1-5, 8-10 and 14-18 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because the claimed invention purportedly lacks utility; and

(c) whether claims 1-5, 8-10 and 14-18 are unpatentable under 35 U.S.C. § 112, second paragraph for alleged indefiniteness.

7. Grouping of Claims

Claims 1-5, 8-10 and 14-18 remain in this case. Claims 1-3, 8, 14 and 15 are independent. All of the claims at issue do not stand or fall together and the separate patentability of claims 1-3, 8, 14 and 15 is particularly addressed in Sections 8.B(1)(c), 8.D(1)(a) and 8.D(2)(a). A copy of the claims on appeal is attached hereto as Appendix A.

8. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Appellant has met their part of the bargain – they have disclosed nucleic acid

molecules which, in their current form, provide at least one specific benefit to the public, for example use to identify the presence or absence of a polymorphism in a population of maize plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecules provide at least these benefits, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acid molecules for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Appellant has distinctly claimed the invention. It is well-settled that claims are to be read through the eyes of one having ordinary skill in the art and in light of the specification. *United States v. Telectronics, Inc.*, 857 F.2d 778, 786, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988). Because the claims read in light of the specification by one of ordinary skill in the art distinctly claim the invention, the requirements of 35 U.S.C. § 112, second paragraph are satisfied.

B. The Claimed Nucleic Acids Have Legal Utility

Claims 1-5, 8-10 and 14-18 stand rejected under 35 U.S.C. § 101 as allegedly not supported by a "specific, substantial asserted utility or a well established utility." Final Action mailed December 31, 2003 ("Final Action"), at page 2. The Examiner has acknowledged that the specification discloses that the claimed invention can be used "to develop nutritionally and agriculturally enhanced crops and products" and "aid gene expression studies that allow the dissection and elucidation of commercially useful traits." Office Action mailed July 16, 2003, at pages 3-4. However, the Final Action asserts the claimed sequence "does not belong in a specific class of genes (for example, a phosphorylase enzyme); and the use set forth is not deemed to be sufficiently substantial such that one skilled in the art can readily use the invention in a real-world sense (for

example, expression of the gene renders the plant disease resistant)." Final Action at page 3.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Appellant has asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, use to identify the presence or absence of a polymorphism, and use as a probe for monitoring gene expression. *See, e.g.*, specification at page 41, line 6, through page 47, line 7 and at page 47, line 16, through

page 50, line 18. Either of these utilities described alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

The Examiner acknowledges that the specification discloses that the claimed invention can be used "to develop nutritionally and agriculturally enhanced crops and products" and "aid gene expression studies that allow the dissection and elucidation of commercially useful traits." *See* Office Action mailed July 16, 2003 at page 4. Moreover, the specification also discloses additional utilities for the claimed nucleic acid molecules,[1] including use of the claimed nucleic acid molecules for isolating a variety of genes, to measure the level of mRNA in a sample,[2] use as molecular markers[3], promoters, and transcriptional regulatory elements, identifying polymorphisms, in cosuppression or antisense expression constructs etc. *See, e.g.*, Specification at page 35, line 9 through page 37, line 17 and starting at page 38 under the heading "Exemplary Uses." The

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[1] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

[2] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, plant growth, quality or yield or combinations thereof.

[3] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

Examiner argues that such uses are not specific because "[A]pplicant's gene does not belong in a specific class of genes...." Final Action at page 3.

(a) Identifying the Presence or Absence of a Polymorphism

More particularly, one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 41, line 6 through page 47, line 4. The Examiner suggests that this utility, like many of the asserted utilities, is not specific or substantial, *see, e.g.*, Final Action at pages 2-3, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms using the claimed nucleic acid molecules is not a legal utility.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates such utilities by asserting that these utilities are not "useful" because they are non-specific uses. *Id.* However, the fact that, *e.g.*, a new and nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107.01 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence, absence or identity of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas

chromatograph itself. Information has been obtained about the gas.[4] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as alfalfa, *Arabidopsis*, barley, *Brassica*, soybean, sunflower, *Phaseolus*, etc.[5] Specification at page 39, lines 3-20. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26,

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[4] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

[5] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules. It is not necessary to disclose what is known. *See, Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using a claimed nucleic acid molecule is the promoter of the gene corresponding to that claimed nucleic acid molecule. Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 40, lines 8-20. The Examiner suggests that such a utility is not specific. Final Action at pages 2-3. This is not correct. The claimed nucleic acid molecules, isolated from maize, are particularly useful, for example, to isolate promoters functional in maize tissues. *See, e.g.*, specification at page 7, lines 17-21 and page 40, line 21 through page 41, line 5.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *e.g.*, chromosome walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acid molecules. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter active in maize plants. *See, e.g.*, specification at page 7, lines 17-21, page 39, line 3 through

page 41 and Examples at page 59, line 1, *et. seq*. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a <u>better</u> starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(c) Claims 1, 3-5 and 8-10 are separately patentable

The Examiner argues that the claimed nucleic acid molecules lack utility apparently because "[A]pplicant's gene does not belong in a specific class of genes...." Final Action at page 3. The Examiner additionally argues that "one skilled in the art would not be able to use a gene of unknown function to achieve real-world benefits without further research." Such a basis for rejection, even if valid, would not apply to claims 1, 3-5 and 14-18, which do not recite a "molecule that encodes a protein." The Examiner provides no evidence that a gene function is necessary to use the claimed nucleic acid molecules for the disclosed utilities, for example, as probes, to detect the presence or absence of polymorphisms, and in DNA mapping, all of which have been asserted in the specification.

As previously stated, the claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101, even if the sequence does not code a gene "in a specific class of genes."

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

The Final Action also suggests that the disclosed uses are legally insufficient because they are not "substantial" utilities. Final Action at pages 2-3. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). " 'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[6]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, *e.g.*, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a

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[6] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of nucleic acid molecules is not merely an academic issue; the real world value of such molecules is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of nucleic acid molecules. Like fermentation processes involving bacteria, nucleic acid molecules with cDNA sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for nucleic acid molecule products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Cf. Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of nucleic acid molecules is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-

brained" utilities.[7] A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107.02 at 2100-41.

Appellant has explicitly identified specific and substantial utilities in the specification. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, Appellant contends that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1-5, 8-10 and 14-18 under 35 U.S.C. §101 is improper and should be reversed.

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[7] Examples of incredible utilities are given in MPEP § 2107.01 at page 2100-34, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 1-5, 8-10 and 14-18 stand rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 3. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Claims Particularly Point Out and Distinctly Claim the Subject Matter Which Appellant Regards as Their Invention

Claims 1-5, 8-10 and 14-18 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. According to the Examiner, the terms "substantially purified" and "structural nucleic acid molecule" render the claims indefinite. Final Action at page 4. The Examiner's position is unfounded.

It is axiomatic that claims are always construed in light of the specification, of which they are a part. *Netword L.L.C. v. Centraal Corp.*, 242 F.3d 1347, 1352, 58 U.S.P.Q. 2d 1076, 1079 (Fed. Cir. 2001); *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1118, 1 U.S.P.Q. 2d 1563, 1566 (Fed. Cir. 1987). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would

understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.,* 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert denied,* 112 S.Ct. 169 (1991). A person of ordinary skill in the art would understand the metes and bounds of the claims read in light of the disclosure of the specification.

The specification delineates the scope of the claims such that one of ordinary skill in the art, *e.g.,* a molecular biologist, would understand what Applicants regard as the invention.

(1) The Phrase "substantially purified" is Definite

The Examiner asserts that the definition for "substantially purified" given in the specification is circular in that Applicants defines "substantially purified" as a molecule separated from substantially all other molecules normally associated with it. Office Action mailed July 16, 2003. A definition given in the specification should not be read in a truncated form and taken out of its context. The specification provides that "the term 'substantially purified'... refers to a molecule separated from substantially all other molecules normally associated with it in its native state." *See*, specification at page 8, lines 20-21. Appellant submits that when read in its entirety, "substantially purified" is defined in a manner free of circularity or indefiniteness.

(a) Claims 3-5 and 8-10 Are Separately Patentable

The Examiner rejects claims 1-5, 8-10 and 14-18 because the phrase "substantially purified" is allegedly indefinite. Such a basis for rejection, even if valid, would not apply to claims 3-5 and 8-10, which do not recite a "substantially purified" nucleic acid molecule. In view of the foregoing, the rejection for indefiniteness is improper and the rejection should be reversed.

(2) The Phrase "structural nucleic acid" is definite when read in light of the disclosure

Claims 1-5, 8-10 and 14-18 stand rejected as allegedly indefinite in the recitation of "structural nucleic acid." Final Action at page 4. Appellant respectfully disagrees.

Appellant respectfully points out that the claims are to be read in light of the specification. *See In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert. denied*, 112 S. Ct. 169 (1991). Furthermore, "[t]he mere fact that a term or phrase used in the claims has no antecedent basis in the specification disclosure does not mean, necessarily, that the term or phrase is indefinite. There is no requirement that the words in the claim must match those used in the specification disclosure." MPEP § 2173.05(e).

The specification describes, for example, the use structural nucleic acid molecules in the transformation of plants and in hybridizations. *See, e.g.*, Specification at page 3, lines 10-12, page 5 line 12 through page 6 line 5 and page 8, lines 15-20. Furthermore, claim 8 recites "a structural nucleic acid molecule encoding a protein comprising an amino acid sequence of SEQ ID NO: 45...." A person skilled in the art, reading the specification and the claims as a whole, would readily understand the phrase "structural nucleic acid." As such, the phrase "structural nucleic acid" satisfies the requirements of 35 U.S.C. 112, second paragraph and the rejection should be reversed.

(a) Claims 1-5 and 14-18 Are Separately Patentable

The Examiner rejects claims 1-5, 8-10 and 14-18 because the phrase "structural nucleic acid" is allegedly indefinite. Such a basis for rejection, even if valid, would not apply to claims 1-5 and 14-18, which do not recite the phrase "structural nucleic acid."

Accordingly, a skilled artisan would understand the metes and bounds of the claims read in light of the specification. In view of the foregoing, the rejection for indefiniteness is improper, and the rejection should be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

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APPENDIX A

1. A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 2 or the complement thereof.

2. A substantially purified nucleic acid molecule that encodes a protein comprising an amino acid sequence of SEQ ID NO: 45.

3. A transformed cell or organism comprising a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 2 or the complement thereof.

4. The transformed cell or organism according to claim 3, wherein said cell or organism is a plant cell or plant.

5. The transformed cell or organism according to claim 4, wherein said cell or organism is a plant cell or plant selected from the group consisting of cotton, wheat, maize, teosinte and soybean.

8. A transformed plant having a nucleic acid molecule which comprises: (A) an exogenous promoter region which functions in a plant cell to cause the production of a mRNA molecule; (B) a structural nucleic acid molecule encoding a protein comprising an amino acid sequence of SEQ ID NO: 45, and (C) a 3' non-translated sequence that functions in a plant cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of the mRNA molecule.

9. The transformed plant according to claim 8, wherein said plant is maize.

10. The transformed plant according to claim 8, wherein said plant is soybean.

14. A substantially purified nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 2 or the complement thereof.

15. A substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 2 or the complement thereof.

16. The substantially purified nucleic acid molecule of claim 15, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 95%

sequence identity with a nucleic acid sequence of SEQ ID NO: 2 or the complement thereof.

17. The substantially purified nucleic acid molecule of claim 16, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 98% sequence identity with a nucleic acid sequence of SEQ ID NO: 2 or the complement thereof.

18. The substantially purified nucleic acid molecule of claim 17, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 99% sequence identity with a nucleic acid sequence of SEQ ID NO: 2 or the complement thereof.